



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0235; FRL-9946-75]

Chlorantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of chlorantraniliprole in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested the tolerances associated with pesticide petition number (PP) 5E8371, under the Federal Food, Drug, and Cosmetic Act (FFDCA). Additionally, the Agency is amending the existing tolerance for egg that was inadvertently omitted in a previous action.

DATES: This regulation is effective *[insert date of publication in the Federal Register]*.

Objections and requests for hearings must be received on or before *[insert date 60 days after date of publication in the Federal Register]*, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0235, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the

Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0235 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0235, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 26, 2015 (80 FR 51759) (FRL-9931-74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP) 5E8371 by Interregional Research Project Number 4 (IR-4), 500 College Road East, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)-carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, in or on nut, tree, group 14-12 at 0.02 parts per million (ppm); and fruit, stone, group 12-12 at 2.5 ppm. This petition additionally requested that 40 CFR 180.628 be amended by revising the existing tolerance in or on artichoke, globe from 4.0 ppm to 2.0 ppm; and hop, dried cones from 90 ppm to 40 ppm. Upon establishment of the tolerances associated with (PP) 5E8371, IR-4 requests to remove the following existing tolerances in 40 CFR 180.628: nut, tree, group 14 at 0.04 ppm; pistachio at 0.04 ppm; fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum at 4.0 ppm; cherry, sweet at 2.0 ppm; cherry, tart at 2.0 ppm; plum, chickasaw at 2.0 ppm; and plum, damson at 2.0 ppm. That document referenced a summary of the petition prepared on behalf of IR-4 by DuPont Crop Protection, the registrant, which is available in the docket EPA-HQ-OPP-2013-0235 at <http://www.regulations.gov>.

There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include

occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for chlorantraniliprole, consistent with FFDCA section 408(b)(2).

In the **Federal Register** of February 7, 2014 (79 FR 7397) (FRL-9905-56), EPA established tolerances for residues of chlorantraniliprole in or on fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum at 4.0 ppm; onion, green subgroup 3-07B at 3.0 ppm; peanut, hay at 90 ppm; and peanut at 0.06 ppm. EPA is relying upon those risk assessments and the findings made in the February 7, 2014 **Federal Register** document in support of this action. The toxicity profile of chlorantraniliprole has not changed. Moreover, because EPA is simply lowering the previously assessed tolerance levels (where the EPA assumed tolerance-level residues for all crops and including the tree nut group 14-12 at 0.02 ppm), the previous dietary estimates also do not change as a result of this action. Therefore, the previously published risk assessments that supported the establishment of those tolerances remain valid.

The petitioner requested to lower currently established tolerances for residues of chlorantraniliprole in/on hops dried cones from 90 ppm to 40 ppm and globe artichoke from 4.0 ppm to 2.0 ppm in order to harmonize with the Codex maximum residue limits (MRLs). Crop field trial studies were submitted for hops and globe artichoke that indicate lowering these tolerances are appropriate and will support the existing U.S. registrations. The petitioner also requested to lower the existing tolerance of 4.0 ppm for stone fruit group 12-12, except cherry,

chickasaw plum, and damson plum and remove the cherry, sweet; cherry, tart; plum, chickasaw; and plum, damson tolerances established at 2.0 ppm and establish a tolerance for stone fruit crop group 12-12 at 2.5 ppm to align with the Canadian MRL. EPA has determined that the existing residue chemistry data support this new tolerance level, which is lower than the current tolerances for some commodities and higher for others. Further, the petitioner requested to convert the tree nut crop group 14 to tree nut crop group 14-12 and to remove the tolerance for pistachio to lower the tolerance for the group (and for the now-included pistachio commodity) from 0.40 ppm to 0.02 ppm to harmonize the U.S. tolerance with the Codex and Canadian MRLs. EPA has determined that the existing residue chemistry data support the request for crop group conversion and for lowering the tolerance level.

Furthermore, EPA issued a final rule in the **Federal Register** of September 18, 2013, concerning the addition of certain commodities to the 40 CFR 180.628. The EPA determined that the tolerance level for egg should be increased from 0.2 ppm to 1.0 ppm, and EPA assessed egg using the tolerance of 1.0 ppm in 2013 as well as in February 2014. This was inadvertently omitted from the table in the 2013 Final Rule. Therefore, this document corrects that omission.

Therefore, EPA relies upon the findings made in the February 7, 2014, **Federal Register** document, as well as the review of the additional globe artichoke and dried cones hop field trial data and existing residue chemistry data in support of this rule. EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to chlorantraniliprole residues.

For a detailed discussion of the aggregate risk assessments and determination of safety for these tolerances, please refer to the February 7, 2014, **Federal Register** document and its supporting documents, available at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2013-0235. Further information about EPA's determination that an updated risk

assessment was not necessary may be found in the document, “Chlorantraniliprole (DPX-E2Y45): Petition for Updating Crop Group Tolerances for Nut Tree Group 14-12 and Fruit Stone Group 12-12, and Amending Established Tolerances for Chlorantraniliprole in/on Artichoke Globe and Hop Dried Cones.” in docket ID number EPA-HQ-OPP-2013-0235.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, liquid chromatography mass spectrometry/mass spectrometry (LC/MS/MS); Method uPont-11374, is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Based on the data supporting the petition, EPA has harmonized chlorantraniliprole tolerances in or on artichoke, globe at 2.0 ppm; hop, dried cones at 40 ppm; and nut, tree, group 14-12 at 0.02 ppm with established Codex MRLs.

C. International Trade Considerations

In this rulemaking, EPA is reducing the tolerances for hops, dried cones from 90 ppm to 40 ppm; globe artichoke from 4.0 ppm to 2.0 ppm; lowering the existing tolerance of 4.0 ppm for stone fruit group 12-12, except cherry, chickasaw plum, and damson plum and establishing a lower tolerance for stone fruit crop group 12-12 at 2.5 ppm; and converting and lowering the tree nut crop group 14 and pistachio tolerances to tree nut crop group 14-12 at 0.40 ppm to 0.02 ppm. The petitioner requested these reductions in order to harmonize with Codex and Canadian MRLs. The reduction is appropriate based on available data and residue levels resulting from registered use patterns.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures Agreement, EPA notified the WTO of the request to revise these tolerances on September 14, 2015 as WTO notification G/SPS/N/USA/2778. In this action, EPA is allowing the existing higher tolerances to remain in effect for 6 months following the publication of this rule in order to allow a reasonable interval for producers in the exporting countries to adapt to the requirements of these modified tolerances. On December 14, 2016, those existing higher tolerances will expire, and the new reduced tolerances for artichoke, globe; fruit, stone, group 12-12; hop, dried cones; and nut, tree, group 14-12 will remain to cover residues of chlorantraniliprole on those commodities. Before that date, residues of chlorantraniliprole on those commodities would be permitted up to the higher tolerance levels; after that date, residues of chlorantraniliprole on artichoke, globe; the commodities contained in stone fruit group 12-12 and tree nut group 14-12; and hop, dried cones will need to comply with the new

lower tolerance levels. This reduction in tolerance is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods.

V. Conclusion

Therefore, tolerances are established for residues of chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)-carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, in or on in or on artichoke, globe at 2.0 ppm; fruit, stone, group 12-12 at 2.5 ppm; hop, dried cones at 40 ppm; and nut, tree, group 14-12 at 0.02 ppm. Upon establishment of the aforementioned tolerances, the Agency is removing the tolerances for cherry, sweet at 2.0 ppm; cherry, tart at 2.0 ppm; plum, chickasaw at 2.0 ppm; and plum, damson at 2.0 ppm as they are subsumed within the newly established group 12-12 tolerances. The Agency is adding an expiration date of December 14, 2016 to the existing tolerances for artichoke, globe at 4.0 ppm; nut, tree, group 14 at 0.04 ppm; pistachio at 0.04 ppm; fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum at 4.0 ppm; and hop, dried cones at 90 ppm. Residues of chlorantraniliprole will be covered by these higher tolerances until the expiration date, after which time, they will need to comply with the lower tolerances being established today. Finally, the Agency is amending the existing tolerance for egg (increasing the tolerance level from 0.2 ppm to 1.0 ppm) to finalize its efforts to establish that tolerance in the **Federal Register** of September 18, 2013.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled

“Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 31, 2016.

Susan Lewis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.628, in the table in paragraph (a):

a. Remove the entries for “Cherry, sweet,” “Cherry, tart,” “Plum, chickasaw,” and “Plum, damson;”

b. Revise the entry for “Egg;”

c. Amend the existing entries by adding a footnote for “Artichoke, globe,” “Fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum,” “Hop, dried cones,” “Nut, tree, group 14,” and “Pistachio;” and

d. Add alphabetically the entries for “Artichoke, globe,” “Fruit, stone, group 12-12,” “Hop, dried cones,” and “Nut, tree, group 14-12.”

The additions and revisions read as follows:

§ 180.628 Chlorantraniliprole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* * *
Artichoke, globe ¹	4.0
Artichoke, globe	2.0
* * *	* * *
Egg	1.0
* * *	* * *
Fruit, stone, group 12-12	2.5
Fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum ¹	4.0
* * *	* * *
Hop, dried cones ¹	90
Hop, dried cones	40
* * *	* * *

Nut, tree, group 14 ¹	0.04
Nut, tree, group 14-12	0.02
* * *	* * *
Pistachio ¹	0.04
* * *	* * *

¹ This tolerance expires on December 14, 2016.

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[FR Doc. 2016-13910 Filed: 6/13/2016 8:45 am; Publication Date: 6/14/2016]